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SALMON, KATHERINE D				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/572,905

Applicant(s)

COMBARET ET AL.

Examiner

KATHERINE SALMON

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2008.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-17 is/are pending in the application.
4a) Of the above claim(s) 16 and 17 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 10-15 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/CDC)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

1. This action is in response to papers filed 6/26/2008.
2. Claims 10-17 are pending. Claims 1-9 have been cancelled.
3. Claims 16-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 12/08/2007.
4. This application contains claims 16-17 drawn to an invention nonelected with traverse in the reply filed on 12/08/2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.
5. The following rejections for Claims 10-15 are necessitated by amendment. Response to arguments follows.
6. This action is FINAL.

Withdrawn Objections/Rejections

7. The objection to the specification made in section 4 of the previous office action is moot based upon amendments to the claims.
8. The claim objections made in section 5 of the previous office action is moot based upon the amendments to the claims.

9. The rejection of the claims under 35 USC 112/2nd paragraph made in section 6 of the previous office action is moot based upon amendments to the claims.
10. The rejection of the claims under 35 USC 102(b) made in section 9 of the previous office action as anticipated by Wang et al. is moot based upon amendments to the claims.

Claim Rejections - 35 USC § 112/Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 10-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404,

"Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman*. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

Breadth of the claims

Claim 10 is drawn to a method for determining a good or poor prognosis for a patient suffering from neuroblastoma comprising extracting any biological material from a biological sample, contacting the sample with specific reagents chosen from reagents specific for the target genes exhibiting SEQ ID No. 2, 3, 7, 8, 10, 22, 25, 29, and 34, and determining the expression and analyzing the expression levels of the target genes to determine whether the patient has a good or poor prognosis. Claims 11-12 define the biological sample as any sample taken from any patient. Claims 13-15 define the support and the reagent.

The claims are broadly drawn analyzing any expression level of SEQ ID No. 2,3,7,8,10,22,25,29, and 34 to any prognosis of neuroblastoma (e.g. poor or good) by taking any biological material from any biological sample.

When the claims are read in light of the specification, the specification does not provide predictable guidance for correlating any expression level of SEQ ID No. 2,3,7,8,10,22,25,29, and 34 to any prognosis (e.g. good or poor of any type of prognosis) of neuroblastoma.

The art, as presented below, that such analysis is unpredictable and population specific.

Nature of the Invention

The claims are broadly drawn to analyzing any expression level of SEQ ID No. 2, 3, 7,8,10,22,25,29, and 34 to any type of poor or good prognosis of neuroblastoma.

The invention is in a class of invention which the CAFC has characterized as “the unpredictable arts such as chemistry and biology.” *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 243 F.3d 1316, 1330 (Fed. Cir. 2001).

Teachings in the Specification and state of the art

The specification discloses that there are 6 stages of neuroblastma (stage 1, 2a, 2b, 3, 4, and 4S (p. 2 lines 10-25). The specification asserts that prognosis of neuroblastoma can be determined by analyzing the expression of target genes selected from 37 genes in Table 1 which are expressed differentially depending on whether the patient has good or poor prognosis (p. 3 lines 20-26). However, as discussed in the working example below, the genes were only analyzed with regard to stage 1, 2, 4, and 4S and not Stage 3. Based on the discussions in the art of Takita et al., presented below, it is unpredictable to correlated prognosis of any tumor sample because it is unpredictable the expression levels in stage 3 tumors. It is not clear if Stage 3 tumors have the same correlative expression as Stage 4 tumors.

The claims are drawn to detection of any type of good or poor prognosis. Any prognosis would encompass a determination of specific stages of tumor. The terms “poor prognosis” and “good prognosis” are not defined in the instant specification. As such these terms are very broad and would encompass prognosis of death, treatment, or recovery, however, the instant specification has not provided guidance that these probes sets would be considered good or poor in any type of good or poor prognosis.

Working Examples

23 neuroblastoma samples were collected from patients who were 10.5 months old (p. 23 lines 10-15). 12 samples were in stage 1 or 2, 4 in stage 4s and 7 in stage 4 (p. 23 lines 15-18). Therefore no stage 3 tumors were evaluated.

The specification asserts that patients who died during the study and patients with a stage 4 neuroblastoma were described as patients with poor prognosis (p. 23 lines 23-25). The specification asserts that patients alive and having developed a stage 1, 2, and 4s neuroblastoma were describes as patients with good prognosis (p. 23 lines 23-25). The specification asserts that the analysis was carried out on 8 poor prognosis patients and 15 good prognosis patients (p. 23 lines 27-28).

Ohira et al. (Cancer Letters 2005 Vol. 228 p. 5) teaches that poor prognosis of neuroblastoma depends on age at diagnosis and advanced tumor stage (3 or 4) (p. 5 2nd column 1st full sentence). However, no stage 3 tumors were used in the instant study so therefore it is unknown if stage 3 tumors would have the same expression levels for each sequence.

The specification discloses that total RNA was extracted (p. 23 line 30) and cDNA was synthesized (p. 24). The specification discloses that expression of approximately 10000 genes was analyzed between good prognosis and poor prognosis patients using the Affymetrix U95Av2 GeneChip (p. 25 lines 5-30).

The specification asserts that relevant genes which were correlated with a poor neuroblastoma prognosis were selected (p. 26 lines 28-30). The specification discloses a list of 37 genes which were differentially expressed in poor prognosis versus good

prognosis samples (Table 2 p. 27-28).

The specification discloses the simultaneous expression of the 37 genes of Table 2 in Figure 1 (p. 32 lines 10-25). The specification discloses the simultaneous expression of the 19 genes of Table 4 in Figure 2 (p. 34). The specification discloses the simultaneous expression of the 16 genes of Table 5 in Figure 3 (p. 35). The specification discloses the simultaneous expression of the 12 genes of Table 6 in Figure 4 (p. 36). The specification discloses the simultaneous expression of the 9 genes of Table 7 in Figure 5 (p. 36). Therefore the specification seems to be asserting a correlation of the detection of over or underexpression of 9 genes to prognosis of neuroblastoma in a patient; however, the claims as broadly written encompass any expression level of the combination of sequences.

The predictability or unpredictability of the art and degree of experimentation

Though there is an example in the instant specification, this example has not provided a predictable method to determine prognosis of neuroblastoma based on the unpredictability in the art.

The art teaches associations between expression studies and cancer prognosis are unpredictable and must be reproduced to determine if there is a correlation. Ohira et al. (Cancer Cell April 2005 Vol. 7 p. 337) teaches a method of predicting prognosis of neuroblastoma using cDNA microarray (abstract). Ohira et al. teaches that gene expression analyses for cancer prognosis prediction should pay close attention to the reproducibility of obtained results (p. 345 1st column last paragraph). Ohira et al.

teaches a complete cross validation analysis without introducing any information leakage and an independent test using new samples are necessary (p. 345 last paragraph). Therefore Ohira et al. exemplify that validation of initial screening results is essential. Here in the instant case it is not clear if any of this analysis was undertaken therefore it is unpredictable whether the results observed are adequate basis for a prognostic too.

Postfiling art, Schramm et al. (Clinical Cancer Research 2007 VOL. 13 p. 1459) teaches generating expression profiles of 47 neuroblastoma patients using Affymetrix U95A chip (abstract). Schramm et al. teaches a table of gene whose correlation was expressed and correlated to neuroblastoma outcome (table 2). Though Schramm et al. teaches the determination of prognosis in the same disease using the same microarray chip, the group of genes Schramm et al. asserts is predictive of prognosis does not overlap the genes asserted by the instant specification. Table 1 of the instant specification lists 37 target genes including SEQ ID No. 2,3, 7,8,10,22,25, 29 and 34 (p. 4 Table 1). The specification asserts that SEQ ID No. 2, 3, 7, 8, 25, and 34 are from genes whose function is known but which have never been related to neuroblastoma (p. 5 lines 1-5). The specification asserts that SEQ ID No. 10, 29 are genes whose function is unknown (p. 5 lines 1-5). Therefore, even in the post filing art, the associations of the specific genes expression in the instant specification and prognosis of neuroblastoma is not observed in a method with similar steps using the same array. Therefore it is unpredictable that the gene expression associations observed in the instant specification are reproducible in any neuroblastoma tumor sample based upon the

unpredictability in the art and post-filing art which does not observe the same gene associations.

Takita et al. (Genes, Chromosomes and Cancer 2004 Vol. 40 p. 120) teaches detection of early and late stage tumors using DNA microarray analysis. Takita et al. teaches that although 9 of the 13 early stage tumors and 4 of the 6 advanced stage tumors were classified as being in the same cluster the remaining tumors showed different expression profiles (abstract). Takita et al. teaches that both early and advanced stage tumors are heterogeneous in expression (abstract). Therefore Takita et al. teaches that tumor tissue in the same stage can have different expression profiles because of the heterogeneous nature of each tumor stage.

The state of the art teaches that there is a natural variation in gene expression among different individuals and the difficulty in applying gene expression results. The art of Cheung et al (Nature Genetics 2003 Vol. 33 p. 422) teaches that there is natural variation in gene expression among different individuals. Cheung et al teaches an assessment of natural variation of gene expression in lymphoblastoid cells in humans, and analyzes the variation of expression data among individuals and within individuals (replicates) p.422, last paragraph; Fig 1). The data indicates that, for example, expression of *ACTG2* in 35 individuals varied by a factor of 17; and that in expression of the 40 genes with the highest variance ratios, the highest and lowest values differed by a factor of 2.4 or greater (Fig 3).

The unpredictability of correlating gene expression level to any phenotypic quality is taught in the prior art of Wu (Journal of pathology 2001 Vol. 195 p. 53). Wu teaches

that gene expression data, such as microarray data, must be interpreted in the context of other biological knowledge, involving various types of 'post genomics' informatics, including gene networks, gene pathways, and gene ontologies (p.53, left col.). The reference indicates that many factors may be influential to the outcome of data analysis, and teaches that expression data can be interpreted in many ways. The conclusions that can be drawn from a given set of data depend heavily on the particular choice of data analysis. Much of the data analysis depends on such low-level considerations as normalization and such basic assumptions as normality (p.63 - Discussion). The prior art of Newton et al (Journal of Computational Biology 2001 Vol. 8 p. 37) further teaches the difficulty in applying gene expression results. Newton et al teaches that a basic statistical problem is determining when the measured differential expression is likely to reflect a real biological shift in gene expression, and replication of data is critical to validation (p.38, third full paragraph).

Amount of Direction or Guidance Provided by the Specification

The specification does not provide guidance to correlate any type of poor or good prognosis by detection of expression of SEQ ID No. 2, 3, 7,8,10,22,25,29, or 34.

The art teaches that associations between gene expression and neuroblastoma is unpredictable and is not predictably reproducible.

The skilled artisan, therefore, would have to perform undue experimentation to determine any prognosis of neuroblastoma by detection of any level of expression of any of SEQ ID No. 2, 3, 7,8,10,22,25,29, or 34.

Quantity of Experimentation

The quantity of experimentation in this area is extremely large since there is significant number of parameters, which would have to be studied prior to being able to practice the claimed invention as broadly as written.

The skilled artisan would have to determine the correlation of expression to any poor or good prognosis. The skilled artisan would have to reproducibly correlate expression of any of SEQ ID No. 2, 3, 7, 8, 10, 22, 25, 29, or 34 to type of poor or good prognosis. Further, the skilled artisan would have to determine the correlation to any type of prognosis including death, recovery, and treatment.

The art teaches that there is a high degree of unpredictability in associations between expression and prognosis. Post-filing art teaches a different set of genes are correlative to prognosis even though Schramm et al used the same Affymetrix chip it his method.

This would require significant inventive effort, with each of the many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps.

Level of Skill in the Art

The level of skill in the art is deemed to be high.

Conclusion

Case law has established that '(t)o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *In re Wright* 990 F.2d 1557, 1561. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) it was determined that '(t)he

scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art". The amount of guidance needed to enable the invention is related to the amount of knowledge in the art as well as the predictability in the art. Furthermore, the Court in *Genetech Inc. v Novo Nordisk* 42 USPQ2d 1001 held that "(I)t is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of the invention in order to constitute adequate enablement".

In the instant case, the specification does not provide a predictable association of SEQ ID No. 2, 3, 7, 8, 10, 22, 25, 29, or 34 and determination of any poor or good prognosis of neuroblastoma. Further, the art teaches that such correlations are unpredictable and population specific.

Accordingly, in view of the unpredictability in the art, and the lack of disclosure in the specification and in the prior art and the unpredictability of the art, it would require undue experimentation for one of skill in the art to make and use the claimed invention.

Response to Arguments

The reply traverses the rejection. A summary of the arguments presented in the reply is set forth below with response to arguments following.

The reply asserts that the new amendments to the claims are directed to a method for determining a good or poor prognosis for a patient suffering from neuroblastoma (p. 6 2nd paragraph). The reply asserts that the claims require determination of the expression of each of the target genes and not just one target gene

(p. 6 2nd paragraph).

These arguments have been fully considered but they have not been found persuasive.

Though the claim requires the analysis of SEQ ID No. 2, 3, 7, 8, 10, 22, 25, 29, and 34, therefore is still a high degree of unpredictability in correlation of the expression level to good or poor prognosis. As discussed in the 35 USC 112/Enablement presented above, the claims encompass any good or poor prognosis. This would include prognosis of death, recovery, and treatment, for example. However, the instant specification has not provided guidance to correlate any prognosis type to the expression of the claimed sequences. Further, the claims are drawn to detection of any expression level of the sequences and therefore would encompass the correlation of both under expression, high expression, and no expression changes for each sequence correlative to good or poor prognosis. The art teaches that such correlations are unpredictable. Further, postfiling art (Schramm et al.) discloses such unpredictability in expression because Schramm et al. discloses a determining of good or poor prognosis for a patient using the same affymetrix chip as is used in the instant specification. Though Schramm et al. teaches the determination of prognosis in the same disease using the same microarray chip, the group of genes Schramm et al. asserts is predictive of prognosis does not overlap the genes asserted by the instant specification. Therefore, based upon the guidance in the instant specification and the teaching in the art, it would be unpredictable to make or use the method as claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. In order to have compact prosecution both a 35 USC 102 and a 35 USC 112/Enablement rejection has been made. The teachings in the specification appears to be commensurate with the teaching in Mora et al, however the specification does not appear to add anything further to the teaching of the prior art. Therefore if the specification is found to be enabling the prior art is enabling and therefore the 35 USC 102 will be maintained. However if the specification is found not to be enabling the prior art provides no additional support for enablement.

13. Claims 10-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Mora et al. (Cancer Letters July 2003 Vol. 197 p. 119) as evidenced by Affymetrix Human Genome U95 array (Affymetrix Product Catalog January 2001)

With regard to Claim 10, Mora et al. teaches a method of extracting biological material taken from a patient (p. 123 1st paragraph). Mora et al. teaches contacting the extracted tumors with reagents specific for the Affymetrix Genechip Human Genome U95 Set (p. 123 1st paragraph). As evidence by the instant specification and the catalog, the U95Av2 GeneChip comprises probes representing 10000 genes including

the genes listed in Table 2 (p. 25 lines 10-15 and Table 2). The genes listed in Table 2 include SEQ ID Nos. 2,3,7,8,10,22,25,29, and 34 and therefore the teaching in Mora et al. of the U95 GeneChip Set teaches the limitation of contacting the sample with reagents specific for SEQ ID Nos. 2,3,7,8,10,22,25,29, and 34. Mora et al. teaches determining the gene expression of all 63175 genes/ESTs on the U95 GeneChip Set which would encompass determining the expression levels of probes (specific reagents) to SEQ ID Nos. 2,3,7,8,10,22,25,29, and 34 (p. 123 1st paragraph). Mora et al. teaches analyzing the expression levels of the entire Affymetrix gene set, which would include analyzing expression levels of SEQ ID Nos. 2,3,7,8,10,22,25,29, and 34 (p. 123 1st paragraph and Figure 2). The phrase to "determine whether the patient has a good or poor prognosis" is an intended use of the positive active steps of the claim and therefore carries no patentable weight and does not further limit the claim.

With regard to Claim 11, Mora et al. teaches the biological sample is a tumor sample (e.g. tumor tissue) (p. 123 1st paragraph).

With regard to Claim 12, Mora et al. teaches hybridization and expression detection using an Affymetrix Genechip and therefore it is inherent that for hybridization methodology the biological material would comprise nucleic acids.

With regard to Claims 13-14, Mora et al. teaches the use of the Affymetrix Genechip which is a composition of probes attached to a solid support(e.g. reagents) (p. 123 1st paragraph)(see attachment of product guide showing the microarray with the description of the probes attached to the array).

With regard to Claim 15, Mora et al. teaches the use of the Affymetrix Genechip (p. 123 1st paragraph) which is a microarray (e.g. a biochip).

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE SALMON whose telephone number is (571)272-3316. The examiner can normally be reached on Monday-Friday 8AM-430PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1634

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/Katherine Salmon/
Examiner, Art Unit 1634

/Juliet C Switzer/
Primary Examiner, Art Unit 1634